

RETETPT

Dkt. 43016-A-PCT-US/JPW/AN

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Philip O. Livingston and Friedhelm Helling

U.S. Serial No.: 08/196,154

Filed: November 16, 1995

For : GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21

1185 Avenue of the Americas New York, New York 10036 June 6, 2000

Assistant Commissioner for Patents Washington, D.C. 20231

RECEIVED

JUL 27 2000

Sir:

FOURTH COMMUNICATION TO CORRECT ERROR IN FILING RECEIPT

This Communication is filed to request the issuance of a corrected Filing Receipt in connection with the above-identified application. Upon receipt of the official Filing Receipt for the subject application, a copy of which is attached hereto as **Exhibit A**, applicants' undersigned attorney noticed several errors.

Specifically, the title and the continuing data are incorrect for the subject application.

The title on a corrected Filing Receipt should read as follows:

--GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21--

Also, the continuing data on a corrected Filing Receipt should read as follows:

--CONTINUING DATA AS CLAIMED BY APPLICANTTHIS APPLN IS A 371 OF PCT/US94/00757 01/21/94
AND A CIP OF 08/009,268 01/22/93 ABN—



Philip O. Livingston and Friedhelm Helling

Serial No.: 08/196,154

Filed: November 16, 1995

Page 2

Applicants contend that the correct title and continuing data may be found in the Declaration and Power of Attorney filed November 14, 1995 (a copy of which is attached hereto as Exhibit B) and on the cover page of International Publication No. WO 94/16731, which is the published version of PCT International Application No. PCT/US94/00757 (a copy of which is attached hereto as Exhibit C), of which the subject application is a 371 national stage application. Applicants note that a copy of this publication was submitted with the subject application on July 21, 1995. Accordingly, applicants request that a corrected Filing Receipt be issued.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

John P. White

Reg. No. 28,678

Date

John P. White

Registration No. 28,678 Attorney for Applicants

Cooper & Dunham LLP

1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400

TO-103X lev. 6-99)

FILING RECEIPT



INITED STATES DEPARTMENT OF COMMERCE atent and Trademark Office SSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Vashingt n, D.C. 20231 니그

016 -A-D

DRWGS APPLICATION NUMBER **GRP ART UNIT** FIL EEE REC'D ATTORNEY DOCKET NO. **FILING DATE** 23 \$726.00 43016-A-PCT-26 1 11/16/95 1645 08/196,154

JOHN P WHITE COOPER AND DUNHAM 1185 AVENUE OF THE AMERICAS NEW YORK NY 10036

Ofamer Carles

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the exemination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted the check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please suffinit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

PHILIP O. LIVINGSTON, NEW YORK, NY; FRIEDHELM HELLING, NEW YORK, NY.

CONTINUING DATA AS CLAIMED BY APPLACANT-

THIS APPLN IS A 371 OF PCT/US94/00757 01/21/94 PAT 5,333,920 08/009,628 01/21/93 AND A CON OF

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 03/30/96 \*\* SMALL ENTITY \*\* TITLE GANGLIOSIDE-KLH CONJUGATE VACCINES PLUS OS-21

PRELIMINARY CLASS: 424

DATA ENTRY BY: WILSON, PAMELLA

12 DATE: 07/22/99 TEAM:

- I I RENNI NERDI NARIO BIRRA NINI RENNI RENNI NERDE NINI RENNI RENNI RENNI RENNI RENNI RENNI RENNI NERDE NINI

(See reverse for new important information)



# Beclaration and Power of Attorney

As a below-named inventor, I hereby declare that:  My residence, post office address, and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor life only one name is listed below; or an original, first and joint inventor life plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21  the specification of which licheck one!  is attached hereto.  was filed on January 21, 1994 as	My tesidence, post oblice address, and citizenship are as stated below next to my name. I believe I am the original, birst and sole inventor lib only one name is listed below; of the subject matter which is claimed and bor which a patent is sought on the invention entitled:  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21  the specification of which (check one)  is attached hereto was filled on January 21, 1994 as Application Serial No PCT/US94/00757 and entered the Nationa stage as U.S. Serial No. 08/196,154 and was amended on July 21, 1995 [lif applicable]  I hereby state that I have reviewed and understand the contents of the above-dentified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number County Filing Date Yes			
I believe I am the original, first and sole inventor life only one name is listed below of an original, first and joint inventor life phral names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled;  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21  the specification of which like a specification of which like one is attached hereto.  X was filed on January 21, 1994  Application Serial No. PCT/US94/00757 and entered the Nationa stage as U.S. Serial No. 08/196,154  July 21, 1995  If applicable  I hereby state that I have reviewed and understand the contents of the above-dentified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Priority Claimed Number  Priority Claimed  Yes No	I believe I am the original, first and sole inventor lif only one name is listed below of an original, first and joint inventor lif phiral names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21  the specification of which [check one]	is a below-named inventor, I hereby declare	that:	
cr an original, first and joint inventor life phiral names are listed below? of the subject matter which is claimed and for which a patent is sought on the invention entitled:  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21  the specification of which lcheck one?  is attached hereto was filled on January 21, 1994 as Application Serial No. PCT/US94/00757 and entered the Nationa stage as U.S. Serial No. 08/196,154 July 21, 1995 [if applicable]  1 hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment reserved to above.  1 acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Priority Claimed Number Priority Claimed Number Priority Claimed	cr an original, first and joint inventor life phiral names are listed below? of the subject matter which is claimed and for which a patent is sought on the invention entitled:  GANGLIOSIDE-KLH CONJUGATE VACCINES WITH CS-21  the specification of which	My residence, post office address, and citizens	hip are as stated below	u next to my name.
the specification of which (check one)  is attached hereto.	the specification of which (check one)  is attached hereto.  was filed on January 21, 1994  Application Serial No. PCT/US94/00757 and entered the National Stage as U.S. Serial No. 08/196,154  July 21, 1995  If applicable  I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application for patent or inventor's certificate histed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country Filing Date Yes No	inimal liest and joint inventor lik phise	u names are listed be	low) ca the subject
is attached hereto.	is attached hereto.	EANGLIOSIDE-KLH CONJUGATE VACCINES WITH OS	3-21	•
Application Serial No. PCT/US94/00757 and entered the Nationa stage as U.S. Serial No. 08/196,154 and was amended on July 21, 1995  [lif applicable]  1 hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  1 acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  1 hereby claim foreign priority benefits under Title 35, United States Code, Section 1.19 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country Filing Date Yes No	Application Serial No. PCT/US94/00757 and entered the National Stage as U.S. Serial No. 08/196,154 and was amended on July 21, 1995  [lif applicable]  1 hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  1 acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  1 hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country Filing Date Yes No	the specification of which check one)		
Application Serial No. PCT/US94/00757 and entered the National Stage as U.S. Serial No. 08/196,154  and was amended on July 21, 1995  [if applicable]  I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country Filing Date Yes No	Application Serial No. PCT/US94/00757 and entered the National Stage as U.S. Serial No. 08/196,154  and was amended on July 21, 1995  [if applicable]  I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country Filing Date Yes No	is attached hereto.		•
and was amended on July 21, 1995  [if applicable]  I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37. Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Stage as U.S. Serial No. 08/196, 154  Interest 1995  [if applicable]  Priority Claimed Priority Claimed  Priority Claimed  Filing Date  Yes No	and was amended on July 21, 1995  [if applicable]  I hereby state that I have reviewed and understand the contents of the above- identified specification, including the claims, as amended by any amendment referred to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37. Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country  Filing Date  Yes No	x was filed on Jan	uary 21, 1994	25
identified specification, including the claims, as amended by any amendment reserved to above.  I acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Country  Filing Date  Yes  No	identified specification, including the claims, as amended by any amendment reserved to above.  1 acknowledge the duty to disclose information of which I am aware which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).  1 hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Country  Filing Date  Yes  No		stage as U.S. Serial July 21, 1995	No. 08/196,154
to the examination of this application in accordance with title 37, Code of Teacher Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number Country  Filing Date Yes No	to the examination of this application in accordance with rate 37, Code of reaction Regulations, Section 1.56(a).  I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Country  Filing Date  Yes No	identified specification, including the claim	understand the conte s, as amended by any d	nts of the above imendment referred
of any foreign application(s) for patent of inventor's certificate having also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Country  Filing Date  Yes  No	of any foreign application(s) for patent of inventor's certificate tasks below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:  Prior Foreign Application(s)  Number  Country  Filing Date  Yes No	to the examination of this application in ac	on of which I am awar cordance with Title 3:	e which is materia 1, Code of Federa
Number Country Filing Date Yes No	Number Country Filing Date Yes No	of any foreign application(s) for patent of un	ventos a cerconcare us Los natent os inventos	s certificate having
None	None		Filing Date	
		None		

Siaius



Declaration and Power of Attorney

Application Serial No.

PCT/US94/00757

I hereby claim the benefit under Title 35. United States Code. Section 120 of any United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35. United States Code. Section 112. I acknowledge the duty to disclose material information as defined in Title 37. Code of Federal Regulations. Sections 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Filing Date

January 21, 1994

08/009,268	January 22, 1993	abandoned
And I hereby appoint  John P. White (Reg. No. Norman H. Zivin (Reg. 25, 161); Christopher C. (Reg. No. 30,616); Roll Phillips (Reg. No. 29,0 Matthew J. Golden (Reg. No. 36,479); Kristina L. Kot (Reg. No. 38,232); and and each of them, all c/o Cooper & 10036, Tel. (212) 278-0400, my a to prosecute this application. to m to transact all business in the Pany International Applications we Cooperation Treaty.	Dunham (Reg. No. 22, bert D. Katz (Reg. 691); Richard S. Mil No. 35,161); Albert nstas (Reg. No. 37,86 Lewis J. Kreisler (R. Drham IIP of 1185 Avenue of utorneys. each with full power take alterations and amend metatent and Trademark Office which are based thereon under the contract of	S. RAVIUROV (Reg. No. 031); Thomas G. Carulli No. 30,141); Peter J. ner (Reg. No. 33,970); Wai-Kit Chan (Reg. No. 4); Robert T. Maldonado Reg. No. 38,522), the Americas, New York, New York of substitution and revocation. Into therein, to receive the patent. connected therewith and to file I the provisions of the Patent.
Please address all communication	is, and direct all telephone cal	
John P. White Cooper & Dunham IIP 1185 Avenue of the Ame New York, New York 10 Tel (212) 278-0400 I hereby declare that all stateme	2036 Source made herein of my own	Reg. No. 28,678
statements made on information statements were made with the kare punishable by fine or imprison States Code and that such wit application or any patent issued to	i and belief are believed to knowledge that willful false s onment, or both, under Section llful false statements may	pe (rue; and juriner that these tatements and the like so made 1 1001 of Title 18 of the United
Full name of sole or first joint inventor Philip Or	rdway Livingston	
Inventor's signature fluigh	Time	Gh Ulac
Citizenship United States	Date of	signature 8/24/93
Residence 156 E 79th Stre	eet, New York, NY 10021	
Post Office Address same as 1	residence address	

### Declaration and Power of Attorney

Full name of joint inventor (if any) Friedhelm Helling	
Inventor's signature	Date of signature 8/17/95
Residence 504 E 63rd Street, Apt 25 Post Office Address same as residence	N, New York, NY 10021
Post Office Address	
Full name of joint inventor (if any)	
Inventor's signature	
Citizenship	Date of signature
Post Office Address	
Full name of joint inventor (if any)	
Inventor's signature	Date of signature
Residence	
Post Office Address	

### **PCT**

## ORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5: A61K 45/05, 31/70, A01N 43/08

A1

(11) International Publication Number:

WO 94/16731

H

(43) International Publication Date:

4 August 1994 (04.08.94)

(21) International Application Number:

PCT/US94/00757

(22) International Filing Date:

21 January 1994 (21.01.94)

(81) Designated States: AU, CA, FI, HU, JP, KR, NO, NZ, RU, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

(30) Priority Data:

08/009.268

22 January 1993 (22.01.93)

Published

US

With international search report.

(60) Parent Application or Grant

(63) Related by Continuation

US Filed on Not furnished (CIP)
Not furnished

(71) Applicant (for all designated States except US): SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH [US/US]; 1275 York Avenue, New York, NY 10021 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LIVINGSTON, Philip, O. [US/US]; Apartment 6C, 156 East 79th Street, New York, NY 10021 (US). HELLING, Friedhelm [DE/US]; Apartment 6H, 303 East 71st Street, New York, NY 10021 (US).

(74) Agent: WHITE, John, P.; Cooper & Dunham, 30 Rockefeller Plaza, New York, NY 10112 (US).

(54) Title: GANGLIOSIDE-KLH CONJUGATE VACCINES WITH QS-21

#### (57) Abstract

This invention provides a vaccine for stimulating or enhancing the production of an antibody which recognizes a ganglioside in a subject to which the vaccine is administered. The vaccine is comprised of an amount of ganglioside or oligosaccharide portion thereof conjugated to an immunogenic protein effective to stimulate or enhance antibody production in the subject. The vaccine is further comprised of an adjuvant and a pharmaceutically acceptable vehicle. The invention also provides a method of using the vaccine for treating or preventing cancer wherein gangliosides are on the surface or in the stroma of the cancer cells.